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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,377

09/20/2005

Thomas H Taylor JR.

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46135 7590 01/10/2007  
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EXAMINER

GUTIERREZ, ANTHONY

ART UNIT

PAPER NUMBER

2857

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/550,377	Applicant(s) TAYLOR, THOMAS H	
	Examiner Anthony Gutierrez	Art Unit 2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/20/05</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-11, and 13-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are directed to a judicial exception; as such, pursuant to the Interim Guidelines on Patent Eligible Subject Matter (MPEP 2106), the claims must have either physical transformation and/or a useful, concrete and tangible result. The claims fail to include transformation from one physical state to another. Although, the claims appear useful and concrete, there does not appear to be a tangible result claimed. Merely calculating a concentration would not appear to be sufficient to constitute a tangible result, since the outcome of the calculation step has not been used in a disclosed practical application nor made available in such a manner that its usefulness in a disclosed practical application can be realized. As such, the subject matter of the claims is not patent eligible.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-6, 8-11, 13-22, and 24-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Wittwer et al. (US Patent 6,503,720 B2).

As to claims 1, 3, 5, 6, 8-10, 11, 13, 15, and 26-28, Wittwer et al. discloses for observation of a metric for a test sample, finding where on a usable portion of a standard sigmoid curve (Figs. 5 and 6) the observation lies, wherein the usable portion of the standard sigmoid curve is determined via a second derivative of the standard sigmoid curve (Abstract, and col. 12, lines 14 and 15); and based on a location of the observation on the standard sigmoid curve, calculating a concentration of the substance (col. 12, lines 8-13. See also col. 9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination) wherein the standard sigmoid curve represents a sigmoid curve fit to a plurality of optical density observations (col. 12, lines 10-13) taken of a reference sample having a known concentration of the substance (col. 12, lines 15-25).

As to claim 2, Wittwer et al. discloses that the sigmoid curve is represented via a four-parameter formula (col. 6, lines 4-10).

As to claims 4, 14, 17, 29, and 30, Wittwer et al. discloses determining whether the observation is above a threshold value (col. 8, lines 40-57), wherein the threshold value

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is determined via a first derivative of the standard sigmoid curve (col. 10, line 43- col. 11, line 2, as related to initial concentration determination. See also, col. 4, line 59- col. 5, line 8).

As to claim 16, Wittwer et al. discloses designating a portion between a minimum and a maximum of a second derivative for the sigmoid curve as the usable portion of the sigmoid curve (See Fig. 3A, MAX\_1DER).

As to claims 18-22, 24, and 25, Wittwer et al. discloses that the features of the method of invention can be implemented using a concentration of live cells in a test sample, wherein the test sample is generated by adding test substances to cell cultures to study both inhibition and stimulation of the test substances (col. 11, line 65-col. 12, line 31. See also col. 5, lines 9-29).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7, 12, and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Wittwer et al. (US Patent 6,503,720 B2) in view of Kaastrup (United States Patent Application Publication US 2002/0160012 A1).

Wittwer et al. discloses the use of second-derivative sigmoid methods for

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determining a microbial stimulatory response as addressed above with respect to growth concentrations related to test samples A, B, and C.

Wittwer does not specifically disclose that the concentration indicates an amount of anti-PA IgG in the test sample.

Kaastруп, however, discloses that IgG is an important antibody in the human immune system that reacts with epitopes (or specific antigens) on invading microorganisms leading to the microorganisms' ultimate destruction (paragraphs 0007-0010). Kaastруп further notes that inclusion of an immunostimulating fragment is used to provide a protective immune response against anthrax (0236).

It therefore would have been obvious to extend the method taught by Wittwer et al. to the indication of amounts of anti-PA IgG in the test samples in order to provide continuous reliable determination of the presence and concentration of potentially lethal anthrax, as detected by sampling an individual's immune response.

**Conclusion**

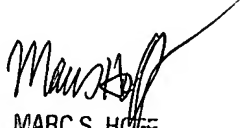
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Gutierrez whose telephone number is (571) 272-2215. The examiner can normally be reached on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc Hoff can be reached on (571) 272-2216. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anthony Gutierrez  
Examiner  
Art Unit 2857

AG  
1/5/07

  
MARC S. HOFF  
SUPERVISORY PATENT EXAMINER  
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